

Lorcaserin (BELVIQ)
Criteria for Use
February 2013; Updated July 2016

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.***

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vaww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive lorcaserin.*

- Pregnancy (Category X; i.e., known pregnancy or positive pregnancy test)¹
- Concurrent use of an selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI), tricyclic antidepressant (TCAs), bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, monoamine oxidase inhibitor (MAOI) in the past 14 days, dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists due to the risk of serotonin syndrome or neuroleptic malignant-like reactions.
- The patient has greater than mild aortic valve regurgitation, or moderate or greater mitral valve regurgitation.
- Known hypersensitivity to lorcaserin
- The patient is taking another weight loss medication (concurrently), e.g., orlistat, phentermine, or topiramate. However, topiramate use for other indications, i.e., migraine prophylaxis, does not exclude the use of lorcaserin.

¹ For women of reproductive potential, obtain a negative pregnancy prior to receiving lorcaserin and patient is provided contraceptive counseling on potential risk vs. benefit of taking lorcaserin if patient were to become pregnant. See **Issues for Consideration**.

Inclusion Criteria *The answers to all of the following must be fulfilled in order to meet criteria.*

- The patient is participating in a clinically supported weight management program that targets all three aspects of weight management (i.e., diet, physical activity, behavioral changes). Weight management treatment programs that target only one or two aspects of weight management are not acceptable. See Issues for Consideration for additional information.
- The patient's BMI is greater than or equal to 30 kg/m² **OR**
- The patient's BMI is greater than or equal to 27 kg/m² in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, metabolic syndrome, obstructive sleep apnea, or degenerative joint disease (osteoarthritis).
- The patient's medication regimen has been reviewed to identify and discontinue medications associated with weight gain when clinically safe and appropriate.

Renewal Criteria *All must be met*

Initial refill after 12 weeks

- The patient is participating in a clinically supported weight management program that targets all three aspects of weight management (i.e., diet, physical activity, behavioral changes). Weight management treatment programs that target only one or two aspects of weight management are not acceptable. See Issues for Consideration for additional information.
- The patient has achieved the weight loss goals at 12 weeks as specified under Dosage and Administration.
- The patient has no contraindications to lorcaserin including pregnancy, hypersensitivity, concurrent use of serotonergic or antidopaminergic medications, or developed new aortic or mitral valve regurgitation.

Criteria for Refills every 6 months (after initial 12 week refill)

- The patient has maintained 67% of their initial weight loss or >5% loss of their baseline total body weight to date or has continued to lose weight
- The patient's BMI is ≥ 24 kg/m²
- The patient has no contraindications to lorcaserin including pregnancy, hypersensitivity, concurrent use

July 2016

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of serotonergic or antidopaminergic medications, or developed new aortic or mitral valve regurgitation.

Dosage and Administration

- One 10 mg tablet by mouth twice a day without regard to meals
- Discontinue if 3% weight loss is not achieved by week 12 as it is unlikely that a meaningful weight loss will be achieved and sustained with continued treatment

Dose in Patients with Renal Impairment

- Dose adjustment is not required in mild renal impairment (CrCl 30 – 60 mL/min). Lorcaserin should be used with caution in patients with moderate renal impairment. Use is not recommended in patients with severe renal impairment or end stage renal disease.

Dose in Patients with Hepatic Impairment

- No dose adjustment is required for patients with mild (Child-Pugh score 5-6) to moderate (Child-Pugh score 7-9) hepatic impairment. Lorcaserin has not been studied in patients with severe hepatic impairment and should be used with caution in such patients.

Monitoring

- Weight
- Pregnancy tests in women of child-bearing potential as deemed necessary by provider and patient
- Glucose and/or signs/symptoms of hypoglycemia in patients with diabetes. Hypoglycemia has been reported following weight loss in patients with type 2 diabetes taking lorcaserin. Adjustment in a patient's diabetes medication may be needed to avoid hypoglycemia.
- Blood pressure (orthostatic) and/or signs/symptoms of hypotension in patients taking antihypertensives or other medications that can lower blood pressure
- Signs and symptoms of valvulopathy
- Signs and symptoms of depression, suicidal thought or behavior, cognitive impairment, or changes in mood

Issues for Consideration

- Clinically supported (i.e., includes group or individual contact with a coach or clinical staff) weight management program that targets more than one aspect of weight management (e.g., VA MOVE!, Weight Watchers, TOPS club, HMR Program, Optifast, Curves Complete, etc.). Clinically-supported web-based or mobile application weight loss programs are acceptable. Weight management treatment programs that target only one aspect of weight management (e.g., Nutrisystem, Curves Fitness, etc.) are not acceptable.

Guidance to determining participation in VA or non-VA weight management program:

Veterans who have documentation of weight management program participation within the past year on at least one occasion.

- Acceptable documentation could include:
 - Clinic notes specifying the provision of weight management counseling or treatment in group or individual formats. Methods of delivery could include face-to-face visits, phone calls, home telehealth, or clinical video telehealth encounters.
 - Evidence that the patient is participating in MOVE! Telephone Lifestyle Coaching (MOVE! TLC).
 - Evidence that the patient is participating in a home telehealth version of MOVE! (sometimes called TeleMOVE! and may be delivered through an in-home messaging device or interactive voice response).
 - Evidence that the patient is using the MOVE! Coach mobile application in conjunction with clinical support provided in-person, by phone, or via secure messaging (MOVE! Coach with Care).
 - Notation from the clinician that the patient is participating in a non-VA, clinically-supported (i.e., includes group or individual contact with a coach or clinical staff) weight management program that targets all three aspects of weight management (e.g., Weight Watchers, TOPS Club, HMR Program, Optifast, Curves Complete, etc.).
 - Clinically-supported web-based or mobile application weight loss programs are acceptable.

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- Weight management treatment programs that target only one or two aspects of weight management (e.g., Nutrisystem, Curves Fitness, etc.) are not acceptable.
 - Lorcaserin has not been studied in patients with heart failure and should be used with caution in these patients. Monitor heart failure patients for changes in heart rate as well as signs and symptoms of heart failure.
 - Persons over 65 years of age were not eligible to enroll in the BLOOM, BLOOM-DM and BLOSSOM trials. Given their lack of representation, caution is advised when treating older adults with lorcaserin.
 - In the clinical trials, lorcaserin was started simultaneously with nonpharmacologic interventions including diet, exercise and behavioral modification. These criteria for use require the patient's weight to have plateaued with these interventions prior to starting lorcaserin. Given this difference, it is unknown if a 3% weight loss 12 weeks after starting lorcaserin is an achievable goal, thus additional flexibility in goal or achieving goal may be necessary before deciding whether or not to continue lorcaserin.
 - Priapism is a potential effect of 5-HT_{2C} receptor agonism. There is limited experience with the combination of lorcaserin and medication indicated for erectile dysfunction (e.g., phosphodiesterase type 5 inhibitors). Therefore, the combination of lorcaserin and these medications should be used with caution.
 - Lorcaserin is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. Maternal exposure to lorcaserin in late pregnancy in rats resulted in lower body weight in offspring which persisted to adulthood. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard of maternal weight loss to the fetus.
A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to the obligatory weight gain that occurs in maternal tissues during pregnancy. The Centers for Disease Control U.S. Selected Practice Recommendations for Contraceptive Use, 2013 may provide guidance for healthcare professionals to be reasonably certain that a woman is not pregnant:
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr62e0614a1.htm?s_cid=rr62e0614a1_w
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